

Message Text

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60

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 NEA-09 ISO-00 OES-05

COME-00 TRSE-00 EB-07 CIAE-00 INR-07 NSAE-00 /067 R

66607

DRAFTED BY: DHEW/FDA:JRWEINROTH, MD

APPROVED BY: OES/SCI/BMP: MBEAUBIEN

DHEW/OIH:MACODDING

ARA/NSC-IG: RJBLOOMFIELD (INFO)

EA/RA:CCHAPMAN (INFO)

NEA/RA:TGRANT (INFO)

NEA/PAB:ASCHIFFERDECKER (INFO)

----- 044588

R 092130Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY KABUL

AMEMBASSY CANBERRA

AMEMBASSY LA PAZ

AMEMBASSY SANTO DOMINGO

AMEMBASSY SAN SALVADOR

AMEMBASSY PORT AU PRINCE

AMEMBASSY ROME

AMEMBASSY KINGSTON

AMEMBASSY TOKYO

AMEMBASSY KUWAIT

AMEMBASSY BEIRUT

AMEMBASSY MEXICO

AMEMBASSY WELLINGTON

AMEMBASSY PANAMA

AMEMBASSY MANILA

AMEMBASSY DOHA

AMEMBASSY BANGKOK

AMEMBASSY CARACAS

AMCONSUL HAMILTON

AMCONSUL HONG KONG

USINT BAGHDAD

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E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, XX

SUBJECT: FDA ADVISORY - FACILITY MANUFACTURING PRACTICES (NON-COMPLIANCE WITH GOOD MANUFACTURING PRACTICES)

1. FDA ADVISES THAT ALL OF THE FOLLOWING PRODUCTS, INCLUDING VARIOUS INTRAVENOUS SOLUTIONS; GLASS BLOOD CONTAINERS; VIALS CONTAINING DILUENTS, ELECTROLYTES, ANESTHETICS, MUSCLE RELAXANTS, AND DEXTROSE INJECTIONS; ALL LOT NUMBERS BEGINNING WITH "G" OR "M" MANUFACTURED BY MCGAW LABORATORIES, DIVISION AMERICAN HOSPITAL SUPPLY CORP., MILLEDGVILLE, GEORGIA ARE BEING RECALLED FROM THE MARKET BECAUSE INSPECTION OF MCGAW'S MILLEDGVILLE, GEORGIA PLANT HAS REVEALED SERIOUS DEVIATIONS FROM CURRENT DRUG GOOD MANUFACTURING PRACTICES. AS A RESULT OF THE INSPECTION, FDA HAS CONCLUDED THAT THERE IS NO ASSURANCE THAT THE PRODUCTS MANUFACTURED UNDER THE CONDITIONS FOUND ARE STERIL AND PYROGEN-FREE.

2. THE FOLLOWING PRODUCTS ARE NOT, REPEAT NOT INVOLVED: HYPERALIMENTATION KITS, HEPARIN, AND STERILE ADMINISTRATION SETS MANUFACTURED AT MILLEDGVILLE, GEORGIA.

3. NO PRODUCTS MANUFACTURED AT GLENDALE, CALIF. PLANT ARE INCLUDED. GLENDALE PRODUCTS DO NOT HAVE THE PREFIXES "G" OR "M". IN THEIR LOT NUMBERS.

4. POSTS ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES HAVE RECEIVED MAILGRAMS DATED FEBRUARY 14, 1975 AND LETTERS DATED FEBRUARY 13, 1975 AND FEBRUARY 20, 1975, REGARDING THE RECALL OF THE ABOVE MENTIONED PRODUCTS.

5. FOREIGN CONSIGNEES AS FOLLOWS:

GENERAL SERVICES OFFICE, AMERICAN EMBASSY DISPENSERY, KABUL
AFGHANISTAN
MCGAW INDUSTRIES PTY. LTD. P.O. 80X433 NORTH SYDNEY, NEW SOUTH
WALES 2060 AUSTRALIA
DISMANA, S.A. CASILLA 5913 LA PAZ, BOLIVIA
J. GASSO, GASSO C POR A, APARTADO 1211, SANTO DOMINGO, DOMINICAN REP
COMMUNIST PARTY OF EL SALVADOR, S.A. EDIFICIO JULIA DE DUCE, SAN SALVADOR, EL
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SALVADOR
DOMINIQUE BAILLY CO. P. O. BOX GQPR PORT AU PRINCE, HAITI
LABORATORY DON BAXTER SPA, P.O. BOX 467 TRIESTE, ITALY
FEDERATED PHARMACEUTICALS CO. LTD. 1 BELL ROAD KINGSTON 11, JAMAICA
TORAY HOSP. SUPPLY CORP. GINZA OHNO BLDG. 4-1-17 TSUKIJI-CHUO-KU,
TOKYO 104, JAPAN
REZAYAT TRADING CO., P.O. BOX 5 KUWAIT IN KUWAIT
LEVANT ALIE HOUSES, P.O. BOX 1780, BEIRUT, LEBANON

FABRIOSA - DIVISION OF AMERICAN HOSP. SUPPLY MEXICO, S.A.
DE C.V., APARTADO NO. 1792 MEXICO 17 D.F.
BENJAMIN LOZANO, CENTRO DE DISTRIBUCION TEJUANA, CALLE CAPELIAS 6
TIJUANA, MEXICO
MCGAW ETHICALS LTD. P.O. BOX 18-069, GLEN INNES, AUCKLAND 6,
NEW ZEALAND
PROMED, S.A. P.O. BOX 6281, PANAMA 5, REP. OF PANAMA
MCGAW-BAXTER LABORATORIES, INC. P.O. 2045 MANILA, REP. OF
PHILIPPINES
AHMED KAHLIL AL-BAKER, P.O. BOX 9, DOHA, QATAR
BANGKOK-SWISS TRADING CO. P.O. BOX 349, BANGKOK, THAILAND
AMERICAN HOSP. SUPPLY CORP., APARTADO 50950, CARACAS 105,
VENEZUELA
KING EDWARD VII MEMORIAL HOSPITAL HAMILTON, BERMUDA
Y.C. WOO AND CO. LTD. 26A-28A DES VOEUX RD., SOLAR HOUSE, 15TH
FLOOR, HONG KONG
MINISTRY OF DEFENSE, DIRECTOR GENERAL OF HEALTH, BAGDAD, IRAQ.
KISSINGER

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUGS, PRIME MINISTER, GOVERNMENT REFORM, ECONOMIC CONDITIONS, FOOD & DRUG REGULATIONS, RECALLS, PRESS CONFERENCES, POLITICAL SITUATION
Control Number: n/a
Copy: SINGLE
Draft Date: 09 APR 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE079613
Document Source: CORE
Document Unique ID: 00
Drafter: DHEW/FDA:JRWEINROTH, MD
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D750122-0887
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19750466/aaaacjbc.tel
Line Count: 133
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: ShawDG
Review Comment: n/a
Review Content Flags:
Review Date: 30 JUN 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <30 JUN 2003 by RuthemTJ>; APPROVED <11 FEB 2004 by ShawDG>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
05 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FACILITY MANUFACTURING PRACTICES COMPLIANCE WITH GOOD MANUFACTURING PRACTICES
TAGS: OGEN, ETRD, TBIO, PINT, PFOR, ES, PO, NATO, (GONCALVES, VASCO)
To: KABUL CANBERRA MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006